

**REMARKS/ARGUMENTS**

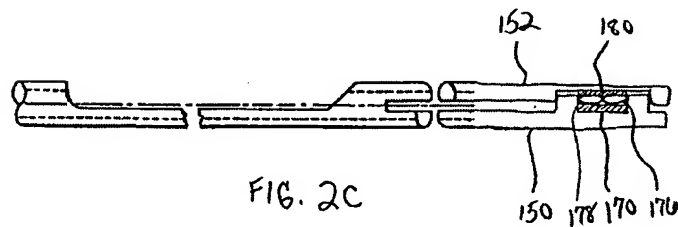
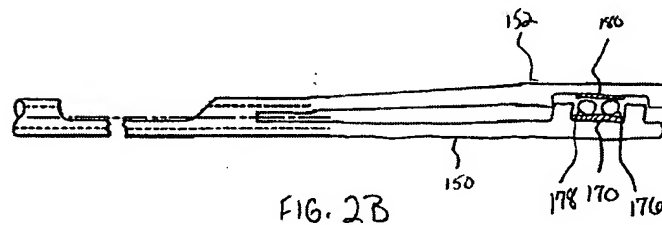
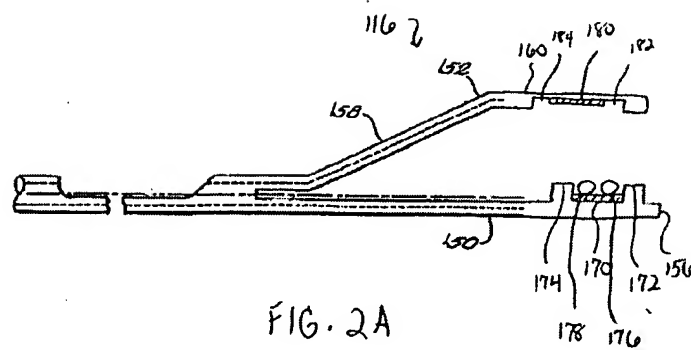
Presently claims 1-8 and 20-34 stand rejected. By this response, Applicants have amended claims 1, 8, 20 and 29.

Specifically, Applicants have amended claims 1, 8, 20 and 29 to recite either a suture welding system or method for fixedly attaching or welding a first length of suture to a separate second length of suture at a suture welding site. Support for these amendments can be found throughout the specification, including, without limitation, at page 9, lines 10-24 and in FIGS. 2A-2C. Accordingly, no new matter is added.

**Applicants' Invention**

The present invention relates to systems, devices and methods for welding lengths of suture to create a fixed attachment between lengths of suture without tying knots. In general, the present invention provides a suture welding device having a suture contacting element with at least one electrode, and coupled to an energy source so that energy can be delivered to first and second lengths of suture in a manner that allows the lengths of suture to be welded to each other. Additionally, as shown in FIGS. 2A-2C (reproduced below), the suture welding device can have pods 172, 174 to restrain the sutures within the grasper 116.

In use, the suture grasper 116 is moved from an open position (FIG. 2A), to an intermediate position (FIG. 2B), and finally to a closed position (FIG. 2C). When the suture grasper 116 is fully closed and two lengths of suture 176, 178 are tightly held within the grasper 116, the lengths of suture 176, 178 can be deformed due to pressure applied to them by the electrodes 170, 180.



Rejections of Applicants' Claims 1, 5, 7 and 20 as Being Anticipated by Morris

In the Final Office Action, the Examiner rejected claims 1, 5, 7 and 20 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,488,690 of Morris et al. Specifically, the Examiner stated:

Regarding Claim 1, 7, and 20, Morris discloses a suture welding system [Column 2, lines 27-33] for fixedly attaching a first length of suture to a second length. Morris also discloses a method of using his welding system. Morris discloses an electrosurgical energy source [Column 3, lines 13-17: "power-supply"], a suture welding device (100) [see Fig. 1], a working end (distal end of

device 100), and a suture contacting element (108). Morris discloses both unipolar and bipolar arrangements for his electrodes [Column 3, lines 10-13].

In his bipolar arrangement [Figure 1], he discloses a first electrode (first wire) electrically coupled to the power supply (a battery or other form of power) disposed on the contacting element (108) for providing electrical energy to the suture [Column 3, lines 10-29]. As part of his bipolar configuration, Morris also discloses a second electrode (second wire) coupled to the battery, which provides a return energy path to the battery. Specifically, Morris describes a “pair of insulated wires” [Column 3, line 26]. Those of ordinary skill in the welding art know that a “bipolar” configuration refers to an arrangement in which current travels from one electrode to another as a part of a complete circuit. Suture is put in the gap between the two electrodes and two lengths are attached to each other [Column 2, lines 38-48]. Figures 1 and 2 show the suture in contact with the suture contacting element (108). Although the respective locations of the tips of the wires are not clear from the disclosure, the *suture is certainly capable of being placed between them*. Figure 1 shows the suture two grasping members and it can be assumed that one wire is in each grasper.

Regarding Claim 5, Morris discloses sutures that are thermoplastics such as nylon [Column 1, lines 26-30.] Such materials are “polymer plastics.”

In the Advisory Action, the Examiner continues to reject claims 1, 5, 7 and 20 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,488,690 of Morris et al., stating, “Morris’ device is fully capable of welding two separate lengths of suture together.”

Applicants disagree with the Examiner’s rejections.

#### The Disclosure of the Morris Reference

Morris discloses a hand-held instrument for coagulating suture knots. [Abstract.] Specifically, Morris teaches a heating element 108 which is formed into a fork-shaped knot retaining feature. [Col. 3, lns. 30-36.] In use, a suture 112 is guided from one side of the wound to the other to form a loop 114. Once the loop 114 is formed, a slider-type knot 110 is pushed down onto the suture 112 such that the loop 114 is tightened. [Id.] The heating element 108 is then activated, and simultaneously seals the knot 110 and cuts the end of the looped suture 112. [Id.]

#### Morris Does not Disclose the Recitations of Applicants’ Claims 1, 5, 7 and 20

Applicants’ claim 1 recites a suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site, comprising separate first and

second lengths of suture; and a suture welding device having a suture contacting element located on the working end wherein provision of electrical energy by the first electrode to the separate first and second lengths of suture welds the separate first and second lengths of suture into a fixed attachment.

As noted above, Applicants' invention creates a fixed attachment between lengths of suture *without tying knots*, and as a result Applicants' lengths of suture are separate. Nowhere does Morris teach or suggest welding *separate first and second lengths of suture*. As noted in the description of Morris, *see Col. 3, lns. 30-36*, a suture 112 is guided from one side of the wound to the other to form a loop 114. Once the loop 114 is formed, a slider-type knot 110 is pushed down onto the suture 112 such that the loop 114 is tightened. The heating element 108 is then activated, simultaneously sealing the knot 110, and cutting the end of the looped suture 112. Thus, Morris is directed to *coagulating suture knots*, and because Morris ties his lengths of suture, they are not separate. Accordingly, because Morris does not teach or suggest welding *separate first and second lengths of suture*, Applicants' claim 1 is allowable over Morris. Further, nowhere does Morris teach a *first electrode on the suture contacting element*, let alone a second electrode, because *Morris does not utilize electrosurgical energy*. Rather, Morris uses a *heating element 108*, and as such would have no need for electrodes. Applicants' claims 5 and 7 are further allowable over Morris, as Morris also fails to disclose the features of these claims.

Applicants' claim 20 recites a method for welding a first length of suture to a separate second length of suture to create a fixed attachment therebetween, comprising providing a suture welding device having a *first electrode* electrically coupled to the electrosurgical energy source and *disposed on the suture contacting element* for providing electrical energy to the separate first and second lengths of suture; and a *second electrode* electrically coupled to the electrosurgical energy source, and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source. As noted above, nowhere does Morris teach or suggest welding *separate first and second lengths of suture*, but rather Morris teaches *coagulating suture knots*. Further, nowhere does Morris teach a *first electrode on the suture contacting element*, let alone a second electrode, because *Morris does not utilize electrosurgical energy*. Rather, Morris uses a *heating element 108*, and as such would have no need for electrodes. Accordingly, Applicants' claim 20 is allowable over Morris.

*Rejections of Applicants' Claims 20, 22-24, 25, 26, 29 and 31-34 as Being Anticipated by Egan '271*

In the Final Office Action, the Examiner rejected claims 20, 22-24, 25, 26, 29 and 31-34 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,358,271 of Egan et al. (Egan '271). Specifically, the Examiner stated:

Regarding Claims 20 and 29, Egan discloses a method for attaching sutures (16 & 18) by providing electrical energy, a welding device (the whole machine), a working end (the distal end of the machine), and a suture contacting element (32). Egan discloses effecting the weld by various means, and although he mainly explains the ultrasonic embodiment, he also discloses employing "electrical arc discharge" to weld the sutures together [Column 3, lines 21-25; Column 6, lines 9-17]. Electrical arc discharge is when an electrical charge moves from one electrode through the air to another electrode. Electrical arc discharge, therefore, requires two electrodes. Egan does not specify which parts of his device would act as the electrodes, but assumedly it would be component (30) and another component.

Regarding Claims 22-24 and 31-33, Figures 15A and 15B show the two opposing (interior), which are movable relative to each other (FIG. 15B). The two sutures are shown in close contact and being constrained laterally by the two interior faces of members (32).

Regarding Claim 25, pods (32A) prevent the suture from sliding out distally.

Regarding Claims 26 and 34, the sutures are made from polydioxanone. [Column 6, line 8.]

In the Advisory Action, the Examiner continues to reject claims 20, 22-24, 25, 26, 29 and 31-34 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,358,271 of Egan et al. (Egan '271). Specifically, the Examiner states:

Egan discloses electrosurgical welding, as evidenced by Column 3, lines 21-25 and Column 6, lines 9-17 of the said reference. Although Egan does not use the word "electrode", since he discloses electrical arc discharge as one of his methods of welding, and discloses metal tips for holding, positioning and otherwise working the sutures, said metal tips can be considered electrodes. An electrode is merely, "A solid electric conductor through which an electric current enters or leaves an electrolytic cell or other medium," and because the mentioned metal tips are capable of having electricity jump from one to another, they are considered to be electrodes, as explained in the final rejection.

Applicants' disagree with the Examiner's rejections.

The Disclosure of the Egan '271 Reference

Egan '271 discloses an ultrasonically welded loop of elongated material, such as a surgical suture, and an apparatus for making the same. [Abstract.] Specifically, Egan '271 teaches a first member 30 which is capable of vibrating and delivering mechanical energy at ultrasonic frequencies, and which moves relative to the second member 32 such that a gap is formed between the members to hold the segments of the loop to be joined together. [Col. 8, Ins. 53-67.] The first and second members 30, 32 also have suture-contacting surfaces 30A, 32A, respectively, which are contoured to promote acoustic coupling and to provide substantially continuous contact with at least one of the segments to be welded. [Col. 9, Ins. 1-7.]

Egan Does not Disclose the Limitations of Applicants' Claims 20, 22-24, 25, 26, 29 and 31-34

As noted above, Applicants' claim 20 recites a method for welding a first length of suture to a separate second length of suture to create a fixed attachment therebetween, comprising providing an electrosurgical energy source, providing a suture welding device having a *first electrode* electrically coupled to the electrosurgical energy source and *disposed on the suture contacting element* for providing electrical energy to the separate first and second lengths of suture; and a *second electrode* electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source.

Contrary to the assertions by the Examiner, Egan '271 does not teach fusing his loop of elongated material by using an *electrosurgical energy source*. Rather, Egan '271 uses *ultrasonic welding*. Ultrasonic welding does not require the use of electrodes, and, it naturally follows that Egan '271 "does not specify which parts of his device act as the electrode," because there are none.

Moreover, as contrary to the Examiner's assertion in the Advisory Action, the metal tips are not electrodes because they do not have an electric current enter or leave them. As the Examiner himself states, "an electrode is merely a solid electric conductor through which an electric current enters or leaves an electrolytic cell or other medium." *Because Egan '271 does not teach or suggest any type of electrical current source, such as an electrosurgical energy source, Egan '271 can in no way have electrodes.* Accordingly, Applicants' claim 20 is

allowable over Egan '271. Further, at least because they depend from an allowable base claim, Applicants' claims 22-24, 25 and 26 are allowable over Egan '271.

Additionally, Applicants' claim 25 recites a suture element that has *at least one pod* configured to prevent the first and second sutures from sliding off of the suture contact element where a first electrode is disposed. Nowhere does Egan '271 disclose at least one pod. As noted above, Egan '271 discloses methods for the ultrasonic welding of a loop of suture material. *Because Egan '271 uses ultrasonic energy, Egan '271 does not have electrodes located in his suture contacting surfaces*, and therefore would have no need to keep a length of suture in proximity to the electrode. Accordingly, Applicants' claim 25 is allowable over Egan '271.

Applicants' claim 29 recites a suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site comprising a suture contacting element disposed on the working end, the suture contacting element having at least one pod configured to prevent the first and second separate sutures from sliding off of the suture contacting element wherein provision of electrical energy by the first electrode to the first and second separate lengths of suture welds the first and second separate lengths of suture into a fixed attachment. Because, as noted above, Egan '271 neither teaches or suggests separate lengths of suture or pods, Applicants' claim 29 is allowable over Egan '271. Further, because they depend from an allowable base claim, Applicants' claims 31-34 are also allowable over Egan '271.

**Rejections under 35 U.S.C. § 103**

**Rejections of Applicants' Claims 1, 3, 4 and 28 as Being Unpatentable in Light of Tetzlaff in view of Egan '324**

In the Final Office Action, the Examiner rejected claims 1, 3, 4 and 28 under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,277,117 to Tetzlaff et al. in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). Specifically, the Examiner stated:

Regarding Claim 1, Tetzlaff discloses a welding device capable of welding suture having two electrodes (110/120), an energy source ("electrosurgical generator") [Column 6, lines 31-33], and a suture contacting element [Column 1, lines 34-42]. His invention is intended for use in welding

body tissue, but is certainly capable of welding suture as well. The working end is end of the device, which grips the material. He does not disclose first and second lengths of suture.

However, Egan teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, melting the tips together with a machine such as Tetzlaff's would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff's machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily.

Applicants disagree with the Examiner's rejection.

*The Disclosure of the Tetzlaff Reference*

Tetzlaff discloses bipolar forceps having a disposable electrode assembly for sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue. [Col. 1, lns. 6-10.] The electrode assembly includes a housing which is removably engageable with the mechanical forceps and a pair of electrodes which are attachable to a distal end of the housing, and which reside in opposing relation relative to one another. [Col. 2, lns. 34-41.]

*The Disclosure of the Egan '324 Reference*

Egan '324 discloses a fastener which combines several functions in a single- or multiple-piece suture retaining device. That is, the fastener guides one or more suture strands into the device, and retains the suture strands in a desired orientation within the device so that applied energy effects bonding of the strands to each other and/or to the suture retaining device. [Col. 3, lns. 37-44.] The energy is applied to the external surface of the device by an ultrasonic weld horn, or a source of laser or thermal energy. [Col. 5, lns. 7-11.]

*Tetzlaff in view of Egan '324 Does not Disclose the Recitations of Applicants' Claims 1, 3, 4 and*

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As noted above, Applicants' claim 1 recites a suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site, comprising



separate first and second lengths of suture; and a suture welding device having a suture contacting element located on the working end wherein provision of electrical energy by the first electrode to the separate first and second lengths of suture welds the separate first and second lengths of suture into a fixed attachment.

Tetzlaff discloses a device which is used in *sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue*, and Egan discloses a fastener which uses *ultrasonic energy to bond one or more suture strands* to each other and/or to the suture retaining device. Neither reference, either alone or in combination, teaches or suggests a *suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site, comprising separate first and second lengths of suture wherein provision of electrical energy* by the first electrode to the separate first and second lengths of suture welds the separate first and second lengths of suture into a fixed attachment. Accordingly, Applicants' claim 1 is allowable over Tetzlaff in view of Egan '324, and at least because they depend from an allowable base claim, Applicants' claims 3, 4 and 28 are also allowable over Tetzlaff in view of Egan '324.

Further, Applicants' claim 28 recites a suture contacting element that has at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element upon which a first electrode is disposed. No where does Tetzlaff or Egan '324 disclose such a feature. Rather, Tetzlaff discloses bifurcated detents 122 which are used to assist in the *cauterizing of tissue*. [Col. 6, Ins. 50-55.] Egan '324 does not remedy the deficiencies of Tetzlaff. Rather, as noted above, Egan '324 discloses a fastener which uses *ultrasonic energy to bond one or more suture strands* to each other and/or to the suture retaining device. *Because Egan '324 uses ultrasonic energy*, Egan '324 has no electrodes on his fastener, and therefore would have no need to keep a length of suture in proximity to the electrode. Accordingly, Applicants' claim 28 is allowable over Tetzlaff in view of Egan '324.

*The Examiner has not Established a Prima Facie Case of Obviousness with Respect to his Rejections of Applicants' Claims 1, 3, 4 and 28 as Being Unpatentable in Light of Tetzlaff in view of Egan '324*

MPEP § 2142 states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations... The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.

Because, in the Final Office Action, the Examiner has not shown any motivation to combine Tetzlaff with Egan '324, any reasonable expectation of success of such combination, and that Tetzlaff combined with Egan '324 teaches or suggests all of the limitations of Applicants' claims, the Examiner has not met the basic requirements for establishing a prima facie case of obviousness.

As noted above, Tetzlaff discloses a device which is used for sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue, and Egan '324 discloses a fastener which uses ultrasonic energy to bond one or more suture strands to each other and/or to the suture retaining device. As the Examiner acknowledged, *Tetzlaff is used for cauterizing human tissue*. However, contrary to the assertion of the Examiner, *nowhere does Tetzlaff suggest that its device can be used in welding suture*. Given that human tissue and suture are two vastly different materials with different welding concerns, there would be no motivation to combine Tetzlaff with Egan '324.

Further, and contrary to the assertion of the Examiner, it would not have been "obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff's machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily." As can be seen by Tetzlaff and Egan '324, the state of the art at the time of Applicants' invention was to either to use ultrasonic energy to combine sutures (Egan '324) or use an electrode assembly for cauterizing human tissue (Tetzlaff), and not to melt two lengths of suture together, effecting a surgical closure. The claimed invention is the first suture welding device to employ radio frequency waves in order to facilitate the welding of sutures. Thus, in his rejection, the Examiner is taking knowledge gleaned from Applicants' disclosure.

"[I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142. Accordingly, for the reasons above, the Examiner fails to make his case of prima facie obviousness and Applicants' claims 1,

3, 4 and 28 are allowable over Tetzlaff in view of Egan '324.

Rejections of Applicants' Claims 1, 2, 8 and 27 as Being Unpatentable by Rydell in view of Egan '324

In the Final Office Action, the Examiner rejected claims 1, 2, 8 and 27 under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 5,342,359 to Rydell in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). Specifically, the Examiner stated:

Regarding Claim 1, Rydell discloses a system capable of welding suture having two electrodes (34/36) [Column 4, lines 65-66], an energy source ("energy source" – see Abstract), and a suture contacting element (distal end of device). His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well. Rydell discloses a "bipolar" instrument, which means that one of the electrodes will provide electrical current and the other will provide for return of the current to the source when the two electrodes come in contact with each other. He does not disclose first and second lengths of suture.

However, Egan teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, melting the tips together with a machine such as Tetzlaff's would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff's machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily.

Applicants disagree with the Examiner's rejection.

The Disclosure of Rydell

Rydell discloses a device to cauterize tissue having three concentric tubes, wherein the outer tube is generally rigid, the central tube is an electrically conductive metal in communication with an energy source, and the inner tube is electrically non-conductive. [Abstract.] The distal end of the central tube extends beyond the distal end of the outer tube and functions as an electrode and first jaw of the coagulation instrument. [Id.] The inner tube, which is translationally movable by an operator, has extending therethrough (within its lumen) a conductive lead whose distal end protrudes distally therefrom and is configured at its distal end

to function as an opposing second jaw to the first jaw. [Id.] When the inner tube is moved translationally, the second electrode jaw is forced towards the first electrode jaw to bring the jaws into contact with each other. [Id.] Thereafter, when current is introduced to the conductive lead and to the central tube, the resulting electrode jaws can cauterize tissue at the treatment site when such tissue is grasped within the jaws.

*Rydell in view of Egan '324 Does not Disclose the Recitations of Applicants' Claims 1, 2, 8 and 27*

As noted above, Applicants' claim 1 recites a suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site, comprising separate first and second lengths of suture; and a suture welding device having a suture contacting element located on the working end wherein provision of electrical energy by the first electrode to the separate first and second lengths of suture welds the separate first and second lengths of suture into a fixed attachment.

Rydell discloses a device to *cauterize tissue* when such tissue is grasped within the electrode jaws, and Egan '324 discloses a fastener which uses *ultrasonic energy* to bond one or more suture strands to each other and/or to the suture retaining device. Neither reference, either alone or in combination, discloses a *suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site, comprising separate first and second lengths of suture wherein provision of electrical energy* by the first electrode to the separate first and second lengths of suture welds the separate first and second lengths of suture into a fixed attachment. Accordingly, Applicants' claim 1 is allowable over Rydell in view of Egan '324, and at least because they depend from an allowable base claim, Applicants' claims 2 and 27 are also allowable over Tetzlaff in view of Egan '324.

Additionally, Applicants' claim 8 recites a suture welding system for fixedly attaching a first length of suture to a separate second length of suture at a suture welding site wherein the suture welding device includes a piston slidably disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and second separate lengths of suture into contact with at least one electrode. Neither reference, either alone or in combination, disclose such a feature. Rather, and contrary to the assertion of the Examiner, not only does

Rydell's device engage tissue, but the inner tube 16 of Rydell has a distal end which is configured to have electrode jaws 34, 36. [Col. 4, ln. 31-col. 5, ln. 60.] In use, it is the electrode jaws 34, 36, not the inner tube 16, which contacts and then cauterizes the tissue. Egan '324 does not remedy the deficiencies of Rydell because Egan '324 discloses a fastener which uses *ultrasonic energy* to bond suture strands. Accordingly, Applicants' claim 8 is allowable over Rydell in view of Egan '324.

*The Examiner has not Established a Prima Facie Case of Obviousness with Respect to his Rejections of Applicants' Claims 1, 2, 8, and 27 as Being Unpatentable in Light of Rydell in view of Egan '324*

Because, in the Final Office Action, the Examiner has not shown any motivation to combine Rydell with Egan '324, the Examiner has not met the basic requirements for establishing a prima facie case of obviousness.

In fact, the Examiner does not even address any motivation to combine Rydell with Egan '324. Rather, the Examiner merely reiterates his statement from a previous rejection which does not even address Rydell:

Conversely, melting the tips together with a machine such as *Tetzlaff's* would *provide uniform tension* in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention *to use Tetzlaff's machine to melt two lengths of suture together*, effecting a surgical closure, in order to close a wound effectively and more easily. (emphasis added).

Moreover, there is no motivation to combine Rydell with Egan '324. As noted above, Rydell teaches a device to cauterize tissue by use of electrodes and Egan '324 discloses a fastener which uses ultrasonic energy to bond one or more suture strands to each other and/or to the suture retaining device. As the Examiner acknowledges, Rydell is used for *cauterizing human tissue*, however, and contrary to the assertion of the Examiner, nowhere does Rydell suggest that its device can be used in welding suture. Given that human tissue and suture are two vastly different materials with different welding concerns, there would be no motivation to combine Rydell with Egan '324.

Accordingly, for the reasons above, the Examiner has failed to make a case of prima facie

obviousness, and Applicants' claims 1, 2, 8 and 27 are allowable over Rydell in view of Egan '324.

*Rejection of Applicants' Claim 6 as Being Unpatentable in Light of Morris in view of Doddi*

In the Final Office Action, the Examiner rejected claim 6 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,488,690 to Morris in view of U.S. Patent No. 4,052,988 to Doddi et al. Specifically, the Examiner stated:

Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.

The Applicants disagree with the Examiner's rejection.

*Morris in view of Doddi Does not Disclose the Recitations of Applicants' Claim 6*

Applicants' claim 6 recites first and second lengths of suture that are made out of polydioxanone.

In no way does Morris, either alone or in combination with Doddi, teach or suggest the recitations of Applicants' claim 6. As noted above, Morris teaches a hand-held instrument for *coagulating suture knots*. [Abstract; Col. 2, Ins. 26-30.] Nowhere does Morris teach using electrodes, as Morris *heat-seals the suture knots*. [Id.] While Doddi discloses synthetic absorbable sutures and other surgical devices that are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof, *nowhere does Doddi disclose the welding of said sutures*. [Abstract.] Accordingly, even if Morris and Doddi could be combined, the combination does not disclose all of the features of Applicants' claim 6.

Further, there is no motivation to combine the Morris and Doddi references. The heating element in Morris is not capable of *welding* any suture material, let alone, polydioxanone. Further, just because polydioxanone sutures are known does not mean that they can be welded. In fact, an express goal of the claimed invention, the first suture welding device of its type, is to

employ radio frequency waves in order to facilitate the welding of polydioxanone sutures. Accordingly, Applicants' claim 6 is allowable over Morris in view of Doddi.

*Rejection of Applicants' Claims 21 and 30 as Being Unpatentable in Light of Egan '271 in view of Rydell*

In the Final Office Action, the Examiner rejected claims 21 and 30 under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,358,271 B1 to Egan et al. (Egan '271) in view of U.S. Patent No. 5,342,359 to Rydell. Specifically, the Examiner stated:

Egan does not disclose radio frequency waves as an energy source, but this is a well known alternative energy source to ultrasonic and electric arc discharge, as demonstrated by Column 1, lines 12-18 of U.S. Patent No. 5,342,359 to Rydell. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use RF energy instead of electric arc discharge, as it is an alternate and analogous means of applying energy in surgical applications.

Applicants disagree with the Examiner's rejection.

*Egan '271 in view of Rydell Does not Disclose the Recitations of Applicants' Claims 21 and 30*

Applicants' claim 21 recites a method for welding a first length of suture to a second length of suture wherein the electrosurgical energy source generates radio frequency waves. Similarly, Applicants' claim 30 recites a suture welding system wherein the electrosurgical energy source generates radio frequency waves.

In no way do Egan '271 and Rydell, either alone or in combination, teach or suggest the recitations of Applicants' claims 21 and 30. As noted above, Egan '271 discloses a fused loop of elongated material, such as a surgical suture, made by an *ultrasonic welding technique*, see Abstract, and Rydell discloses a device to *cauterize tissue*. [Abstract.] While Rydell does employ the use of radio frequency energy, *Rydell's purpose is to cauterize tissue, not to weld suture*. Given that human tissue and suture are two vastly different materials with different welding concerns, it would be impracticable for one skilled in the art to combine Egan '271 with Rydell. Accordingly, Applicants' claims 21 and 30 are allowable over Egan '271 in view of Rydell.

Conclusion

In view of the above, each of the presently pending claims (1-8 and 20-34) in this application is in condition for immediate allowance. Accordingly, the Examiner is asked to pass this application to issue.

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Respectfully submitted,

By 

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